Adherence and patients’ experiences with erlotinib.

Gepubliceerd: 25-05-2009 Laatst bijgewerkt: 18-08-2022

The present study aims to get more insight into the various aspects that govern adherence to the oral anticancer drug erlotinib in daily practice.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON26332

Bron
Nationaal Trial Register

Verkorte titel
Caper

Aandoening

Cancer
Oral chemotherapy
Erlotinib
Adherence
Plasma concentration

Longkanker
Orale chemotherapie
Erlotinib
Therapietrouw
Plasmaconcentratie

Ondersteuning

Primaire sponsor: VU medical centre, Amsterdam
Overige ondersteuning: Roche Nederland B.V.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Adherence rate; a patient is adherent with the intake of 85% or more of the prescribed medication;
2. Plasma concentration of erlotinib;
3. Number and grade of side-effects.

Toelichting onderzoek

Achtergrond van het onderzoek

Background of the study:

Adherence to treatment is a complex and multifaceted issue that can substantially alter the outcomes of therapy. Variation in plasma concentration may be due to variability in pharmacokinetics. Even in a clinical trial setting there is a considerable variability in efficacy and side effects of erlotinib. In a less controlled environment, like the use of erlotinib in daily practice, adherence may also play a significant role. Only few studies have focused on the use of oral anticancer drugs in daily practice and the influence of adherence to its effectiveness. Information about the reasons for non-adherence among non-small-cell-lung cancer (NSCLC) patients taking the oral anticancer drug erlotinib is essential for the development of interventions that may increase adherence.

Objectives of the study:

Primary Objective: To study the relationship between adherence and the plasma concentration of erlotinib and to study the relationship between side effects and adherence to erlotinib in patients with NSCLC.

Secondary Objective: The second part of this study is of an explorative nature. The relationships between patient characteristics, disease characteristics, side effects, quality of life, patients beliefs and attitude towards disease and medicines, adherence, dose adjustments and plasma concentration of erlotinib in patients with NSCLC will be studied.

Study design/methods:

Prospective observational cohort study in which 50 patients starting with treatment with

erlotinib will be followed up until 16 weeks. NSCLC patients of 18 years or older under treatment in one of the participating hospitals in the Netherlands starting with erlotinib can be included. Before the start of therapy with erlotinib and during week 3-4, 8-9, 12 and 15-16, patients will be asked to fill in a questionnaire. Furthermore in week 3-4, 8-9 and 15-16 blood samples are collected, which will be analysed for plasma concentration of erlotinib. Adherence will also be measured using an medication event monitoring system (MEMS).

Doel van het onderzoek

The present study aims to get more insight into the various aspects that govern adherence to the oral anticancer drug erlotinib in daily practice.

Onderzoeksopzet

Baseline and [3 or 4], [8 or 9], [12] and [15 or 16] weeks after baseline.

Onderzoeksproduct en/of interventie

None, this is an observational study.
The use of erlotinib in daily practice will be monitored for 4 months.

Contactpersonen

Publiek

L. Timmers
Universitaire Poliklinische Apotheek VUmc,
De Boelelaan 1118, PK 0 hal 54
Amsterdam 1081 HZ
The Netherlands
+31 (0)20 4442777

Wetenschappelijk

L. Timmers
Universitaire Poliklinische Apotheek VUmc,
De Boelelaan 1118, PK 0 hal 54
Amsterdam 1081 HZ
The Netherlands
+31 (0)20 4442777

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

NSCLC patients starting with erlotinib.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Younger than 18 year or insufficient knowledge of the Dutch language.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-07-2009
Aantal proefpersonen:	50
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	25-05-2009

Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1720
NTR-old	NTR1830
Ander register	VUmc, KFA : OZ05KFA00002
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A